Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Qvar® (beclometasone dipropionate) Aerosol, Autohaler® and Easi-Breathe® Abbreviated Prescribing Information:

Presentation: Qvar 50 mcg and 100 mcg Autohaler. Qvar 50 mcg and 100 mcg Easi-Breathe Inhaler. Qvar 50 mcg and 100 mcg Aerosol Inhaler. Qvar contains beclometasone dipropionate in solution in propellant HFA-134a resulting in an extrafine aerosol. **Indications**: Prophylactic management of mild, moderate or severe asthma. **Dosage and administration:** The dose should be adjusted to individual patient needs. Patients should be instructed in the proper use of their inhaler, including rinsing out their mouth with water after use. *Adults, elderly, and children over 12 years: Starting and maintenance dose:* Mild asthma: 100 to 200 mcg daily in two divided doses. Moderate asthma: 200 to 400 mcg daily in two divided doses. Severe asthma: 400 to 800 mcg daily in two divided doses. *Children under 12 years:* No data in children under 12 years of age, hence no dosage recommendation can be made. **Contraindications**: Hypersensitivity to the active substance or any other ingredients. **Precautions and warnings:** Patients should be properly instructed on the use of the inhaler to ensure that the drug reaches the target areas within the lungs. Use regularly. When symptoms are controlled, maintenance therapy should be reduced to the minimum effective dose. Not indicated for the immediate relief of asthma attacks or management of status asthmaticus. Advise patients to seek medical attention for review of their maintenance therapy if their asthma seems to be worsening. Patients receiving systemic steroids for long periods and/or at high doses should have stable asthma before transfer to inhaled steroids. Withdrawal of systemic steroids should be gradual. Severe asthma requires regular medical assessment, including lung-function testing, as there is a risk of severe attacks and even death. Patients should be instructed to seek medical attention if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required as this may indicate deterioration of asthma control. If this occurs, patients should be assessed and the need for increased anti-inflammatory therapy considered (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid). Patients should carry a steroid warning card and have adrenocortical function monitored regularly. Monitor height of children regularly. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Caution in patients with active or latent pulmonary tuberculosis. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. **Interactions:** Qvar contains a small amount of ethanol. There is a theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole. Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents. **Pregnancy and lactation:** There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore, be a risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure. Beclometasone dipropionate is delivered directly to the lungs by the inhaled route and so avoids the high level of exposure that occurs when corticosteroids are given by systemic routes. There is no experience with or evidence of safety of propellant HFA 134a in human pregnancy or lactation. However, studies on the effect of HFA 134a on reproductive function and embryofoetal development in animals have revealed no clinically relevant adverse effects. **Effects on ability to drive and use machines:** Not relevant. **Adverse reactions:** A serious hypersensitivity reaction including oedema of the eyes, face, lips and throat (angioedema) has been reported rarely. Paradoxical bronchospasm. Systemic effects may occur with inhaled steroids, particularly at high doses prescribed for prolonged periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). *Common:* Hoarseness and candidiasis of the mouth and throat may occur. Taste disturbances. Pharyngitis. Consult the Summary of Product Characteristics (SmPC) in relation to other side-effects. **Overdose:** Acute overdose is unlikely to cause problems. Suppression of HPA function following inhalation of large amounts of the drug over a short period. Excessive doses taken over a prolonged period can produce a degree of atrophy of the adrenal cortex in addition to HPA suppression. In this event treat patient as steroid-dependent and transfer to a suitable maintenance dose of a systemic steroid such as prednisolone. Once the condition is stabilised, the patient should restart Qvar as described in the SmPC. **Further information:** AeroChamber Plus® and AeroChamber® devices are compatible with Qvar Aerosol Inhalers. **Price:** Per 200 dose unit: Qvar 50 mcg Aerosol: £7.87, Qvar 100 mcg Aerosol: £17.21 Qvar 50 mcg Autohaler: £7.87, Qvar 100 mcg Autohaler: £17.21, Qvar 50 mcg Easi-Breathe: £7.74, Qvar 100 mcg Easi-Breathe: £16.95. **Legal category:** POM. **Marketing Authorisation Number:** Qvar 50 mcg Aerosol: PL 00289/1371. Qvar 100 mcg Aerosol: PL 00289/1372. Qvar 50 mcg Autohaler: PL 00289/1373. Qvar 100 mcg Autohaler: PL 00289/1374. Qvar 50 mcg Easi-Breathe: PL 00289/1375. Qvar 100 mcg Easi-Breathe: PL 00289/1376. **Marketing Authorisation Holder:** Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom. **Job Code:** UK/MED/17/0089. **Date of Preparation:** October 2017.